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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,408

Applicant(s)

WAKAMIYA, NOBUTAKA

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 11/15/04 have been entered into the record.
- B. Claim 10 has been canceled. New claims 11-17 have been added. Therefore, claims 11-17 are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The objection to the specification has been withdrawn in view of Applicants' amendment to the priority data.

3. Claim Objections

- A. The syntax of claim 12 could be improved by add the word "the" before the terms "presence" and "absence" in part (b).
- B. The syntax of claim 13 could be improved by amending part (d) to recite "transforming a host cell with the vector of part (c)" since the claim, as worded, implies that the vector is being transformed. Furthermore, this amendment would help to clarify which vector is being used.

4. Claim Rejections - 35 USC § 112, first paragraph - enablement

- A. No rejection is being made over claim 13 since, even though parts (d) and (e) do not recite that the host cell is "isolated," the preamble of the claim requires that the protein be purified. Therefore, the claim does not read on the transfection of a host cell for the purposes of gene therapy.

5. Claim Rejections - 35 USC § 112, second paragraph

- A. The rejection of claim 10 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' cancellation of the claim and the fact that the Malhorta reference does demonstrate that the regions claimed in the present invention are well-known in the art.

Art Unit: 1647

B. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: to what the virus-infected cells are being presented in part (b).

C. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a conclusion step which relates back to the preamble and which identifies when the conditions of the preamble have been met. For example, after part (d), add "wherein an inhibition of budding demonstrates that the hMBP possesses anti-Influenza virus activity.

D. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how hMBP can be produced from amplifying a native congenin cDNA. It appears from page 1, line 16 of the specification that hMBP and congenin are different proteins.

6. Claim Rejections - 35 USC § 102

A. Claims 11-17 are rejected under 35 USC 102 for the reasons already of record on page 3 of the Office Action mailed 5/11/04. Applicants argue that the present invention only recites "two units of Gly-Xaa-Xaa" whereas Kawasaki have additional Gly-Xaa-Xaa units. Furthermore, Applicants argue that the protein of the present invention does not require an "N-terminal region-carrying cysteine" as is present in Kawasaki. These arguments have been considered, but are not deemed persuasive. The present claims recite "having a domain structure **comprising...**" Therefore, this is open language. Kawasaki teach a protein which comprises a collagen region consisting the two Gly-Xaa-Xaa, though additional Gly-Xaa-Xaa residues exist in Kawasaki. Furthermore, this open language allows for the presence of an "N-terminal region-carrying cysteine" as is present in Kawasaki. Applicants can overcome this rejection by demonstrating that the additional Gly-Xaa-Xaa residues of Kawasaki are part of the art-accepted region identified as the "collagen region" and, therefore, that the collagen region of Kawasaki consists of more than just the two repeats. As stands, Applicants have argued that these additional residues are present in Kawasaki, but have not shown that these regions are actually in the collagen region.

Art Unit: 1647

6. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 11-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,110,708. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn towards conglutinins/mannan-binding proteins comprising identical regions and using identical primers, vectors, phages and host cells for their production. It would have been obvious to one of ordinary skill in the art at the time of the present invention to have produced the protein of the present invention in light of the '708 patent since it appears that the protein of the '708 patent would meet the limitation of the present claims and that the protein of the present invention would fall under the scope of the '708 patent.

7. Conclusion

A. No claim is allowable.

Art Unit: 1647

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647


ROBERT LANDSMAN
PATENT EXAMINER